UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: OR940019 and WA940034. Esfenvalerate. Comments on Special Local Need [24(c)] Registrations for Use of Esfenvalerate (ASANA®XL) on Blueberry. (CBTS#13986, DP Barcode D204827 and CBTS#13985, DP Barcode #D204829, No MRID #'s).

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The States of Oregon and Washington have both approved a Section 24(c) registration for the use of the pesticide ASANA®XL (a.i.: esfenvalerate; EPA Reg. No. 352-515, 8.4% a.i., 0.66 lb a.i./gallon)) to control adult root weevils on blueberry crops within the each state. Since the SLN use is identical in each state, CBTS comments will be directed to both requests in this memo.

A tolerance is established for residues of the pesticide fenvalerate [(RS)-cyano-(3-phenoxyphenyl)-methyl (RS)-4-chloro-alpha-(1-methylethyl)benzeneacetate] in or on blueberry at 3 ppm (40 CFR 180.379). Fenvalerate is a racemic mixture of four optical isomers (RS, SR, RR, and SS) and was registered for use on crops in the formulated product PYDRIN®2.4EC. Esfenvalerate [(S)-cyano-(3-phenoxyphenyl) methyl (S)-4-chloro-alpha-(1-methylethyl) benzeneacetate] is the insecticidally active

SS-isomer in the racemic mixture and is the active ingredient of ASANA®XL.

Conclusions:

1a. For the purposes of these SLN applications, CBTS concludes that the nature of the residue in/on blueberry consists of parent esfenvalerate.

1b. Since blueberry is not an animal feed item, the nature of the residue in animals is moot.

2. For the purposes of these SLN applications, PAM II methodology is considered adequate for enforcement of the established 3.0 ppm tolerance of fenvalerate in/on blueberry.

3a. The available field residue data submitted and reviewed is for fenvalerate residues in/on blueberry. No data is submitted for esfenvalerate.

3b. For the purposes of these SLN applications, CBTS concludes that the residue data will adequately support the proposed SLN. The established 3.0 ppm tolerance for fenvalerate will adequately cover esfenvalerate residues in/on blueberry.

Recommendations:

CBTS recommends for the establishment of the requested SLN's OR940019 and WA940034 of esfenvalerate to control adult root weevils on blueberry crops within the each state.

Detailed Considerations:

Manufacturing and Formulation

For the purposes of these SLN's, the description of the manufacturing process for esfenvalerate (fenvalerate enriched in the S,S-isomer) is adequate. (See memos of 1/26/84 and 7/10/85, L. Cheng).

The chemical name for esfenvalerate is (S)-cyano-(3-phenoxyphenyl)-methyl-(S)-4-chloro-alpha-(1-methylethyl)-benzeneacetate. The CAS Reg. No. is 66230-04-4.

Technical esfenvalerate contains about 84% esfenvalerate, with the remainder consisting of the other noninsecticidal fenvalerate isomers. The typical isomer composition of the fenvalerate present in PYDRIN®2.4EC and the fenvalerate enriched in esfenvalerate present in ASANA®XL is given in the following table:

Typical Isomer Composition of the Fenvalerate Present in PYDRIN®2.4EC and ASANA®XL

Formulation	% S,S-isomer (esfenvalerate)	% R,S-isomer	% S,R-isomer	% R,R-isomer
PYDRIN®2.4EC	23	27	27	23
ASANA®XL	84	8	7	1

PYDRIN®2.4EC contains 30 weight percent fenvalerate isomers. One gallon contains 2.4 lb total fenvalerate isomers. ASANA® XL contains 0.66 lb a.i./gal (8.4 weight percent of the S,S-isomer, esfenvalerate, or 0.79 lb/gal total fenvalerate isomers (10 weight percent total fenvalerate isomers).

Proposed Use:

A Comparison of Proposed Label and the Residue Data Parameters:

	Proposed Use	Residue Data
chemical	esfenvalerate	fenvalerate
formulation	Asana®XL	PYDRIN®2.4EC
crop	blueberry	blueberry
method of application	ground spray	ground spray
# of applications/ growing season	4	4
timing	14-day PHI	14-day PHI
rate/application	0.05 lb a.i./A	0.2 lb a.i./A
rate/year or season	0.2 lb a.i./A/season	0.8 lb a.i./A/season

Nature of the Residue in Plants:

No plant metabolism studies were submitted for review with these SLN applications.

Metabolism of fenvalerate in plants has been discussed in PP#4F3003 (See memos of 5/1/84, R. Perfetti; 5/3/85, E. Haeberer). Metabolism has also been summarized in Regulatory Aspects of Pyrethroid Metabolism (1985), authored by K. Arne and R. Perfetti.

Studies with fenvalerate labeled in either the chlorophenyl ring or the phenoxyphenyl ring have been conducted on cotton, lettuce,

apples, tomatoes, soybeans and wheat plants. In all studies parent compound remained the major constituent of the residue. The only metabolite found at significant concentrations in these studies was 4-chloro-beta-(1-methylethyl)-alpha-(3-phenoxyphenyl)benzenepropanenitrile [decarboxylated fenvalerate], a photodegradate. TOX determined that this photodegradate was not of concern (See memo of 7/19/84, A. Kocialski). Very little translocation was observed.

Comparative metabolism of esfenvalerate and fenvalerate in cabbage was examined in a paper submitted in support of PP#4F3003: N. Mikami, et. al., Pestic. Sci. 1985, 16, 46-58. (MRID # 412572-03). (See memo of 4/26/90, S. Koepke). These studies indicate that metabolism of esfenvalerate is qualitatively similar to that of fenvalerate, the racemic mixture of the two pairs of optical isomers. Metabolism studies done to support the registration of fenvalerate are applicable to esfenvalerate.

The ingredient of concern in PYDRIN®2.4EC is fenvalerate, i.e. a racemic mixture of all four isomers of (R,S)-cyano-(3-phenoxyphenyl) methyl (R,S)-4-chloro-α-(1-methylethyl) benzeneacetate. The active ingredient of Asana is esfenvalerate, i.e. the (S,S) isomer. However, while only the (S,S) isomer is considered the active ingredient, all four isomers are considered to be residues of concern.

Therefore, the nature of the residue in plants, and specifically in blueberry for these SLN's, is adequately understood.

Nature of the Residue in Animals:

For the purposes of these SLN applications, since blueberry is not an animal feed item, the nature of the residue in animals is moot.

Analytical Methodology:

No analytical methodology studies were submitted for review with these SLN applications. The residue analytical method for fenvalerate, AMR-717-87/MMS-R-478-1, appears as Method I in the Pesticides Analytical Manual, Volume II (PAM II).

The registrant's residue analytical method for esfenvalerate utilizes a capillary GC column which provides baseline resolution of the diastereoisomer pairs (RS+SR) and (SS+RR). This method is very similar to the method previously validated by EPA for fenvalerate.

Fenvalerate is completely recovered by FDA multiresidue methods 1, 2 and 4. Recoveries of esfenvalerate should be identical.

Therefore, adequate enforcement methodology is available for the requested SLN's.

Magnitude of the Residue:

Residue data from field trials for esfenvalerate were not submitted with these requested SLN 24(c) registrations. Residue data were submitted from field trials in WA using fenvalerate. Residue data (fenvalerate) for OR were taken from PP#5E3242. Residue data (fenvalerate) are also available in the same petition for the states of MI, ME, NJ, NC ,and WA (same data as submitted in the SLN request).

Site	Rate, lb a.i/A	# of appl.	Type of appl.	Spray, GPA	PHI, in days	ppm,	Percent Recovery, (Fortified level)
OR	0.2	4	grd	150	14	0.75, 0.69	97, 88
WA	"	"	"	100	"	1.2, 1.5	103, 101
MI	"	"	"	"	"	1.2, 1.5	96, 105
ME	"	"	"	10.4, 23	"	1.6, 2.0	103, 94
NJ	"	"	"	85	"	0.94, 0.90	113, 99
NC	"	"	"	100	"	0.18, 0.33	73, 98

Tolerances for blueberry 40CFR §180.379 are based on residue studies conducted with PYDRIN®2.4EC. No bridging data has been submitted for blueberry. The registrant, E.I. du Pont de Nemours, has proposed to convert fenvalerate tolerances to esfenvalerate tolerances based on bridging data.

Because much less total fenvalerate isomers from ASANA®XL need be applied to achieve the same activity as from the PYDRIN®2.4EC fenvalerate isomers, it follows that the tolerances established on the basis of PYDRIN®2.4EC residue trials will be higher than tolerances established from ASANA®XL residue trials. However in both cases, the residue analytical method determines the total concentration of fenvalerate isomers, and tolerances are established for the total isomers.

Therefore, for the purposes of these SLN's only, the residue data and the established 3 ppm tolerance for fenvalerate will adequately cover the expected esfenvalerate residues in/on blueberry.

Storage Stability Data:

No storage stability data has been submitted for the proposed use. However, studies submitted previously have shown that fenvalerate is stable in ginned cottonseed stored at -20°C for 99 weeks and apples, alfalfa, and sorghum grain stored at -10°C for 21 months. (PP#4F3021, memo of E. Haeberer, 5/15/84). The storage stability data is adequate for the requested SLN's.

Meat, Milk, Poultry, and Eggs:

Since blueberry is not an animal feed item, residues of esfenvalerate are not expected in livestock meat, meat byproducts, milk, or eggs from the proposed SLN registrations.

cc: J. Stokes (CBTS); esfenvalerate SLN 24(c); R.F.; Circu.
RDI: PErrico:07/22/94: RLoranger:07/22/94
7509C:CBTS:JStokes:js:Rm 803:CM#2:305-7561:07/25/94